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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,004	09/09/2003	Mei Zhong	21402-608 (Cura 908)	3491
30623	7590	09/21/2005	EXAMINER	
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111			MONDESI, ROBERT B	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/659,004

Applicant(s)

ZHONG ET AL.

Examiner

Robert B. Mondesi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-38 is/are pending in the application.
- 4a) Of the above claim(s) 22, 23 and 25-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21, 24 and 31-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## **DETAILED ACTION**

This Office action is in response to the amendment filed July 13, 2005. **Claims 21, 24, 31 and 33-38** are presently pending and under examination.

### ***Restriction requirement***

This application contains **claims 22-23, 25-30** are drawn to an invention nonelected with traverse in Paper filed January 28, 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicants are informed that as indicated previously the further election requirement is not considered to be a species election but rather a requirement for an election of a patentably distinct product.

Applicants elected SEQ ID NO: 104 in Paper filed January 28, 2005. The pending claims will be examined as far as they relate to the elected subject matter; furthermore, **claim 30** is considered to be drawn to patentably distinct product and has been withdrawn for pertaining to non-elected subject matter. Applicants are reminded that the restriction was made final in the previous Office action, mailed April 11, 2005/

### ***Withdrawal of Objections and Rejections***

The objections and rejections not explicitly restated below are withdrawn.

### ***Maintenance of rejections***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC 101 § 112***

**Claims 21, 24 and 31-38** remain rejected under U.S.C 101 because the claimed invention is not supported by either specific and substantial asserted utility or well-established utility.

**Claims 21, 24 and 31-38** remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set in the previous Office action, one skilled in the art clearly would not know how to use the claimed invention.

***Claim Rejections - 35 USC § 102***

**Claims 21, 24 and 31-38** are rejected under 35 U.S.C. 102(e) as being anticipated by Mack et al. US Patent No: 6,762,020.

The above rejections were explained in the Office action.

***Response to applicant's arguments***

In regards to the rejection of the **claims 21, 24 and 31-38** under U.S.C 101 and 112, first paragraph the applicants assert that they have clearly shown that NOV9d shares primary structural similarity with the LIV-1 human protein and it is evidenced further that the instant application teaches that NOV9 sequences share high homology to L1V-I protein (see, e.g., Example 9, pages 116-127).

Applicants assert further that by providing the sequence of NOV9d, it is also apparent to a skilled person in the art that NOV9d is a splice variant of L1V-I simply by performing a sequence alignment of the two genes.

Applicants also submit that the instant specification teaches a specific, substantial and credible utility of the claimed nucleic acids for differentiating certain breast cancer cells from corresponding normal tissues. For example, the specification at, e.g., page 50, line 33, to page 54, line 6, teaches how to detect the presence or absence of the claimed nucleic acids in a biological sample. Example 9 (pages 116-127) teaches that NOV9 family of genes is highly homologous to LIV-1, which is known to be highly expressed in certain breast cancer (see, e.g., McClelland et al., Br. J. Cancer 77(10): 1653-1656 (1998) Oestrogen-regulated genes in breast cancer: association of pL1V-1 with response to endocrine therapy"). The instant application at pages 185-194 gives a working example and clearly shows that a nucleic acid sequence encoding a member of NOV9, NOV9a, is over expressed in certain breast cancer cells as compared to corresponding normal tissue (see, e.g., panels 1.3D, 2.2, and 2D). Therefore, the specification teaches how to use the claimed nucleic acids to differentiate certain breast cancer cells from normal breast tissue.

Applicants' arguments have not been found persuasive. As stated previously in the Office action mailed April 11, 2005, function prediction from structure or structure prediction from function is not a reliable measure of utility. Nov9d human protein encoded by novel Nov9d polynucleotide has been assumed to be homologous to human LIV 1 like proteins but since the function of Nov9d polypeptide is not known it would not be conclusive to assume, solely based on structure homology, that they have the same function and would have the same utility. It is necessary to carry out further

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characterization of this protein to assess the patentable utility, of the polynucleotide. In another words, just because a person skill in the art would recognize that perhaps the nucleic acid molecule of the invention, indeed, encodes a splice variant of a LIV-1, it does not also mean that the nucleic acid molecule of the invention also encodes a polypeptide that has the same function as that of the LIV-1 protein. If the applicants feel that the examiners assertion is incorrect they are welcomed to submit a declaration, which indicates that the LIV-1 splice variant of the present application has the same function as the LIV-1 protein.

Furthermore it must be pointed out that the sections of the specification of the present application that the applicants refer to do not provide any evidence of utility for the specific claimed nucleic acid molecule of the invention. On pages 50, lines 33 to page 54, line 6 the applicants discuss a variety of methods and assays wherein nucleic acid molecules can be used; however there is not a single mention of the NOV9d polypeptide, the nucleic acid molecule that encodes the NOV9d polypeptide or SEQ ID No: 104, nor is there any indication that any of these methods or assays specifically pertain to the claimed nucleic acid molecule of the invention. The applicants are reminded that the utility requirement guidelines under 35 U.S.C are clear with regards to "specific" and "asserted" utility. Applicants have failed to provide any indication of specific utility for the claimed nucleic acid molecule of the invention since they have failed to indicate whether any of the mentioned assays or methods is specific to the claimed nucleic acid molecule.

Applicants' assertion with regards to the expression of NOV9d in certain types of breast cancer cells is not understood, since the working example on pages 185-194 that the applicants refer to is NOV9a and not NOV9d. The examiner does not understand the rationale behind the indication of the over expression of a nucleic acid molecule that encodes NOV9a in breast cancer tissue (compared to the corresponding normal tissue). The claimed nucleic acid molecule of the invention encodes NOV9d not NOV9a, and even though, as the applicants have stated the two proteins may be part of the same family and may both be splice variants of the same LIV-1 protein, the indication of the over expression of one protein is not evidence of the over expression of another protein in the same family. It may be a good clue as to whether the homologous family member may also be over expressed and worth further study, but in no way is an indication that NOV9d, is also, over expressed in breast cancer tissue as compared to normal tissue.

In regards to the rejection of **claims 21, 24 and 31-3** under 35 U.S.C. 102(e) as being anticipated by Mack et al. US Patent No: 6,762,020, the applicants assert that Mack et al. disclose the BCR4 gene (SEQ ID NO: 5, which is encoded by SEQ ID NO: 1 or 4, see, column 3, line 58, to column 4, line 22, and Figs. 1-3).

Applicants further assert that as shown in "Appendix A (attached hereto)," SEQ ID NO: 104 of instant application is a splice variant of BCR4; therefore it is apparent that SEQ ID NO: 104 is not identical to BCR4.

Applicants' arguments have not been found persuasive. The rejected claims use the transitional phrase "comprising" which is considered to be open language. It is apparent from the applicants own submission of Appendix A that the nucleic acid

molecule disclosed by Mack et al. encodes an amino acid sequence that comprises that of SEQ ID NO: 104.

***Conclusion***

No claims are allowed

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

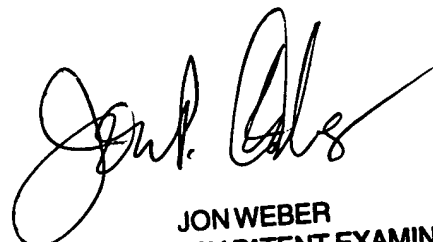
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Robert B. Mondesi  
Patent Examiner  
Group 1653  
09-15-05

  
JON WEBER  
SUPERVISORY PATENT EXAMINER